Iatrogenic Complications in Surgery

Five Years' Experience in General and Vascular Surgery in a University Hospital

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Advances in medicine that have led to more sophisticated methods of diagnosing, treating and monitoring patients take an ever increasing toll in iatrogenic complications.[1-3] It may be argued that the net effect is an improvement in care, but it is self-evident that minimizing iatrogenic complications will increase the benefit to the patients of the ever increasing complex methods of treatment. Iatrogenic complications tend to be sporadic and varied in nature, and are difficult to study as a group. Psychological and medicolegal problems add to this difficulty. However, if the incidence of iatrogenic complications is to be decreased, a concerted effort has to be made to study them. This report deals with such an effort.

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IN 1976 A PROGRAM was launched of prospective monitoring of all iatrogenic complications by recording them in a separate section of the death and complication (D & C) report. An interim summary was made at the end of two years (Period A: January 1976–December 1977), at which time some change was made in the mode of gathering the information. Prospective monitoring was continued for three more years (Period B: January 1978–December 1980), and the present report summarizes all the available information from both study periods.

Materials and Methods

The hospital is a 1050-bed, tertiary-care, public medical facility affiliated with a medical school. There are over 40,000 admissions and approximately 400,000 outpatient clinic visits per year. The surgical service from which part this report was constructed is a 30-bed service performing general and peripheral vascular surgical operations. The staff is all full time and consists of three qualified surgeons, three to four residents, and one or two interns. The senior staff is also in charge of vascular consultations for the whole hospital, as well as for the general surgical consultation for two out of the eight medical services in the facility.

The proportion of vascular operations performed by the service varied between 35 and 40% during each of the five years of the study, averaging 38% for the whole period. There was no private practice, and between 60 and 65% of operations were performed by the residents. Three other general surgery services operate in the hospital, but all peripheral vascular surgery consults and operations are performed by this service.

All deaths and complications were recorded, discussed weekly, and reported monthly. A complication was defined as any untoward event that was not part of the smooth recovery from operation, and that increased or caused morbidity and/or mortality. An iatrogenic complication was defined as any complication resulting from a diagnostic or therapeutic procedure that was not the natural consequence of the interaction between the procedure and the patient's disease or was not an expected outcome of the procedure.

Iatrogenic complications were divided into three grades of severity: 1) severe—causing death, a life-threatening situation, major amputation, or moderate to severe permanent disability; 2) moderate—causing temporary disability or mild permanent disability, leading to an operation or reoperation or causing considerable prolongation of hospitalization time; 3) mild—causing added discomfort but no disability or undue lengthening of hospitalization.

In order to try and understand the "etiology" of these iatrogenic complications, they were divided arbitrarily into six subgroups.

1) Accidental: those in whom the complication appeared to be unavoidable and not related to human error

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TABLE 1. *Number of Patients with Iatrogenic Complications and Comparison with Wound Infection Rates (Periods A and B)*

Year	Number of operations	Iatrogenic Complications		Wound Infections (all wounds)	
		No.	Percent	No.	Percent
1976/77	1423	140	9.8	54	3.8
1978	746	52	7.0	27	3.6
1979	765	47	6.1	41	5.3
1980	802	47	5.9	25	3.1
Total	3736	286	7.6	147	3.9

but rather to some very unusual or rare circumstance, or to an unusual reaction of the patient, or to unexpected failure of material or a piece of equipment.

2) Faulty technique or routine: complications that arose as a result of not adhering fully to an accepted protocol, or failing to execute a routine procedure in the proper manner. In order to be included under this heading, the procedure had to have been performed by an adequately trained or supervised person. These were usually one-time errors performed under pressure of time or external circumstances.

3) Errors in judgement or management: there is a fine, somewhat arbitrary line between categories 2 and 3. An act leading to an iatrogenic complication was considered erroneous if, when performed by a qualified person, the mistake was a gross one, or if performed by an unqualified person, or without adequate supervision.

4) Failure to identify correctly an anatomical structure, or failure to interpret a radiograph or laboratory finding may lead to a complication due to inappropriate action. This may happen to qualified surgeons or other personnel as well as to the unqualified. Under this heading were included only bona fide errors, not those made by the inexperienced without supervision. The latter were classified as errors under 3.

5) Adverse reaction to drugs was a separate category including allergies, toxicity, accidental overdose, untoward results of withdrawal, and complications of anticoagulant and fibrinolytic treatment.

6) Various complications occurring as a result of anesthesia, general or local, made up the final group.

Although the assignment to each of these groups was clear in most cases, some cases were difficult to classify. The senior surgeon's judgment was then used for the final decision.

Results

During period A, there were 1423 operations and 140 iatrogenic complications (9.8%), of which ten were severe, 29 moderate and 101 mild. Of the mild iatrogenic complications, 71 were infusion thrombophlebitis that were severe enough to cause an elevation of body temperature, leading to a fever workup. Excluding infusion phlebitis, there were 69 iatrogenic complications, giving an incidence per operation of 4.1%. For comparison the wound infection rate for all wounds (clean, contaminated, and dirty) during the same period was 3.8%.

The routine for administration of intravenous fluids and medications was then modified, achieving some decrease in the incidence of infusion phlebitis. The total number of iatrogenic complications and a comparison with the wound infection rates for all wounds for the corresponding periods is given in Table 1. For all periods the rate of iatrogenic complications exceeded the wound infection rate.

Because of the population of elderly patients with peripheral vascular diseases on this service, there is a special awareness of the importance of venous thromboembolism and cardiac complications. Table 2 gives the figures during period B for venous thromboembolism, cardiac complications, and iatrogenic complications. Even with infusion phlebitis excluded, the number of iatrogenic complications exceeded the combined number of venous thromboembolic and cardiac complications in each of the three years. The number of deaths caused by iatrogenic complications was identical to that caused by venous thromboembolism and somewhat less than the number of cardiac deaths. This count

TABLE 2. *Comparison of the Number of Patients with Iatrogenic Complications,* Venous Thromboembolism and Cardiac Complications (Period B)*

Year	Iatrogenic Complications*		Venous thromboembolism		Cardiac Complications	
	No.	(No. Fatal)	No.	(No. Fatal)	No.	(No. Fatal)
1978	30	(3)	11	(2)	10	(2)
1979	37	(2)	7	(2)	16	(6)
1980	39	(2)	10	(3)	14	(4)
Total	106	7	28	7	40	12

* Excluding infusion phlebitis.

TABLE 3. *Operations for Arterial Iatrogenic Complications (Period B)*

Year	Total No. Arterial Operations	No. for Vascular Trauma	Iatrogenic Vascular Trauma	Percent Iatrogenic of all Arterial Operations
1978	173	27	21	12
1979	186	20	15	8
1980	205	25	19	10
Total	564	72	55	10

of fatal iatrogenic complications includes only those that were the direct or major cause of death. It does not include iatrogenic complications in sick patients that could have contributed to death of the patient.

During period B, 564 arterial operations were performed, of which 72 were done for repair of vascular trauma. Iatrogenic vascular trauma was responsible for 55 of these operations, *i.e.*, 76% of vascular arterial injuries and just under 10% of all arterial operations (Table 3).

Of the above 55 operations, 43 were performed to repair damage caused by diagnostic or therapeutic arterial catheterizations (Table 4). The rate of complications requiring surgical corrections was less than 1% for adults, for both the Seldinger approach used by the radiologists and the left heart catheterizations. For children the rates were 4.3 and 2.3%, respectively. The remaining 12 cases of operation for iatrogenic arterial trauma were performed for five perforations of arteries by the Fogarty balloon catheter, four cases of accidental arterial damage during nonvascular operations, and three complications of intra-aortic balloon pumping.

Other iatrogenic common subgroups of complications during period B are enumerated in Table 5. The high proportion of neurologic complications is related to the specific types of operations performed in this department, namely, vascular operations, sympathectomies both lumbar and upper-dorsal, and operations for thoracic outlet syndrome. The total number of iatrogenic complications (Tables 3 and 5 and some miscellaneous) is greater than the total number of patients in Table 2, as some patients had two distinctly separate iatrogenic complications.

During period B, 902 consultations were given in all areas of the hospital, mainly for vascular problems, as explained in the material and methods section. Iatrogenic complications (moderate and severe only) accounted for 9% of these consultations according to the details given in Table 6.

The total added mortality and morbidity caused by iatrogenic problems of all grades of severity during the five-year period (A and B) is given in Table 7. The list is weighted toward certain types of iatrogenic complication because of the specific nature of this surgical practice, but it is reasonable to assume that these are just part of the total damage caused by diagnostic and therapeutic procedures in this hospital. No attempt was made to place a dollar value on this impressive list, but the waste of human resources and the suffering resulting from the iatrogenic epidemic of modern medicine and surgery is self-evident.

Table 8 classifies the iatrogenic complications of period B according to their causes or associated conditions. The headings in the table are explained in the material and methods section. The total number somewhat exceeds the total for period B in Table 1, since in a few cases there were two distinct factors operating.

Almost 40% of iatrogenic complications were classified as accidental, and almost one quarter were due to faulty techniques or failure to adhere to routines. Drugs were responsible for 18% of iatrogenic complications, and just over 10% were attributed to errors. The latter type of complication of course is the least acceptable, and unfortunately it accounts for about one fifth of complications classified as moderate or severe, and for just over one third of those classified severe. It is clear that this type of iatrogenic complication should be the first target for all efforts to reduce the danger that exists to patients in the hospital environment.

TABLE 4. *Rates of Iatrogenic Arterial Damage Requiring Operative Repair After Angiography Performed by the Seldinger Approach and After Left Heart Catheterization (Period B)*

	No. of Examinations	No. of Operations	Percent
Seldinger	1880	18	0.96
Adults	1810	15	0.8
Children*	70	3	4.3
Cardiac cath	1912	25	1.3
Adults	1144	7	0.6
Children*	768	18	2.3

* Up to 13 years of age.

TABLE 5. *Some Common Iatrogenic Complications (Period B, Excluding Arterial Injuries)*

Neurological:		23
Neuralgia, paraesthesia	10	
Paralysis, Palsy	11	
Accidental section (one complete)	2	
Subclavian puncture:		12
Major	3	
Minor	9	
Drugs:		27
Overdose, toxicity, allergy, withdrawal	15	
Anticoagulants (8 major, 4 minor)	12	

Discussion

This report cannot be considered comprehensive, but rather it represents a sample of the specific types of iat-

TABLE 6. *Iatrogenic Complications during Period B (Moderate and Severe Only) Encountered During Consultations on Other Services*

Arterial (Seldinger, cardiac cath, accidental injections, arterial lines)	67
Venous (Pacemakers, catheters, hematomata extravasation, septic phlebitis)	9
Others	5
Total: 9% of 902 consultations.	81

TABLE 7. *Mortality and Morbidity from Iatrogenic Complications (Period A & B): Vascular Service and General Hospital Consultations Combined*

Death: Cause 11; Contributory 16	27
Major amputation of an extremity	7
Surgery or additional surgery required	87
Disability, permanent damage	56
Prolongation of hospitalization	60
Added discomfort only	243

rogenic complications created by and encountered by surgeons in a specialized type of service. It is certain, however, that no area in surgery or medicine is immune from iatrogenic complications.[1-5] A recent report estimates that between 5 to 8% of hospital patients suffer some type of injury or insult as a result of treatment,[6] a figure entirely consistent with these results.

The main impact of iatrogenic complications is on the patient, who may be temporarily or permanently disabled, or may even lose his life. There are several ways in which the economic damage can be quantified,[3] and this includes damages paid after litigation in some cases, although it is estimated that even in the U.S. only one in 100 affected patients will sue.

It should be stressed that the fact that a complication is iatrogenic in no way means that the act leading to it was negligent. Even when an error has been performed, the question of malpractice has to be examined separately.[8] Even so, the economic damage is not negligible,[3] and a lawsuit may be quite unsettling for the surgeon's ego. Still, the main concern is with the suffering of the patients, especially when that suffering may have been avoided.

Iatrogenic diseases are the topic of many recent reports, and they have been given several names such as surgical mishaps,[3] misadventures,[7] or adverse occurrences.[1] In the medical specialties, drug-induced illness or adverse drug reaction are the usual names.[9] But regardless of how they are called, or whether they occur on surgical or medical services, they deserve much more attention than they usually get.

Certain types of complications that occur in surgical patients draw a lot of attention and are the subject of many studies, and their prevention is a subject for concentrated efforts. Acquired hospital and surgical wound infections, venous thromboembolism, and cardiac complications of surgery are three examples. Specific preventive measures are routinely practiced, and a lot of resources are put into programs directed at decreasing the incidence of these complications.

As shown in the present study, iatrogenic complications are no less frequent and cause morbidity and even mortality that is comparable to any of those groups of complications. Yet the literature on iatrogenic complications is much more sporadic, and the practical approach to them is more hesitant. This is particularly true in the surgical specialties. In the nonsurgical specialties, a drug or drug combination is often viewed as the cause of the disease, while in surgery the act or the error leading to the complication is usually committed by the surgeon or is a direct result of his decision. A natural tendency to rationalize, and a reluctance to discuss errors openly prevents a serious approach to this problem.

Surgical iatrogenic complications may be quite devastating, especially if not recognized on time. The postoperative patient is more difficult to evaluate. The iatrogenic complications are sometimes so bizarre and unexpected that diagnosis is delayed to a point when the damage is difficult or impossible to repair. In one study of surgical misadventures, the cost in morbidity and mortality as well as in economic terms was staggering.[3,7]

It is probable that human fallibility or unexpected failure of material or equipment cannot be eliminated completely. But they can be reduced if a concerted effort is made to study the causes, to educate the medical and paramedical personnel, and to continuously monitor the quality of care and re-evaluate medical practices, taking their potential for iatrogenic complications into account. A prerequisite is a method of reporting and analyzing every iatrogenic complication.

The causes of iatrogenic complications vary from hos-

TABLE 8. *Causes or Associated Factors in Iatrogenic Complications (Period B)*

	Severity of Iatrogenic Complication			Total	
	Severe	Moderate	Mild	No.	Percent
Accidental	3	11	44	58	38.5
Faulty technique or routine	3	16	17	36	24.0
Errors	6	5	5	16	10.7
Improper identification or interpretation	2	3	—	5	3.4
Drugs	2	6	19	27	18.0
Anasthesia mishaps	1	1	6	8	5.4
Total	17	42	91	151	100.0

pital to hospital as well as within different areas of a single hospital. They depend on the type of patient population, the level of sophistication of care, and on manpower policies. The shortage of physicians, causing them to work long hours or making them unavailable at a site of emergency, as well as nursing and technical personnel shortage may have a profound effect on the patient's safety. If these causes are unrecognized, they will not be corrected. Therefore, it is essential to have an individual or a committee monitor iatrogenic complications. Some hospitals are now initiating patient safety plans or risk management programs, and the American College of Surgeons has developed a Patient Safety Manual that could be of help in such programs.[10]

The activity of such a committee is sure to have some benefit. Information will be gathered, and each incident can be investigated while fresh in the mind of the parties involved. Whether and to what degree this type of activity will also reduce the incidence of iatrogenic complications remains to be seen, and probably depends upon the ability to tackle the real problems.

It is unlikely that there will be a single set of actions that will decrease or prevent iatrogenic complications. Unlike other classes of complications in surgical patients, such as infections, venous thromboembolism, and cardiac or pulmonary complications, iatrogenic complications are quite heterogenous and usually occur sporadically, although here or there may be a small "epidemic." They also occur in different areas of the hospital. The surgeon or his team may be only indirectly involved or even not at all. Because of the team approach to patient care, it may not be apparent who is responsible for reporting the iatrogenic complication.

The war against iatrogenic diseases in general and in surgery in particular should be waged on two fronts. The first includes a general awareness of their existence and their danger to patients; improved recording in charts; close communication between the various disciplines involved in patient care; providing the optimum in terms of manpower, materials, and equipment; and a real-time reaction and scrutiny with drawing of specific conclusions from every more-than-trivial iatrogenic complication. The conclusions should be educational and not punitive, and the whole atmosphere should be one encouraging open discussion.

The second front is continuous monitoring of the particular setup in each hospital and on each service. A periodic summary may sometime reveal a small "epidemic" connected with a piece of equipment that is used by many. If unreported and unrecorded, each person may view the mishap as accidental, but the sum of several such accidents will surely point to the need for some action. Such an "epidemic" may be related to a staff shortage, to a particular individual, to a faulty batch of materials or catheters, or to a less-than-optimal routine. Some iatrogenic complications arise from the use of a new device or a new type of material or drug when the medical staff is not completely aware of all the technical aspects and possible complications. A mechanism should be set up to ensure that all new routines are studied in detail by all those involved in their application. Corrective actions would depend on the underlying cause, and would be the same whether the iatrogenic complication was a sporadic event or part of an "epidemic."

It is essential to create an atmosphere that is conducive to a free discussion of all possibilities. Fear of litigation may consciously or subconsciously result in misinterpretation and rationalization to the detriment of the particular patient whose problem is being attempted to solve and of other patients who may be subjected to the same risk in the future. Ideally, iatrogenic complications should be tackled on a medical and scientific basis, being entirely divorced from legal consideration. In practice this is probably not possible, but as physicians and surgeons, we should be concerned mainly with improving patient care. The resulting decrease in litigation would be a welcome byproduct.

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